DEC 14 2005

5.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K052645

5.1 Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Phone: (585) 453-3143
Fax: (585) 453-3368
Contact Person: Michael M. Byrne

5.2 Date of Preparation:

9/23/05

5.3 Device Proprietary Names:

Trade Names	VITROS Chemistry Products Calibrator Kit 28
	VITROS Chemistry Products FS Calibrator 1
	VITROS Chemistry Products ASO/RF Performance Verifier I and II
Common Name	Antistreptolysin O calibrators and controls

5.4 Classification Names

Classification Name: Calibrator (21 CFR 862.1150): Class II

Classification Name: Quality Control material (assayed and unassayed) (21 CFR 862.1660): Class I: Reserved

5.5 Predicate devices

The VITROS Chemistry Products Calibrator Kit 28, VITROS Chemistry Products FS Calibrator 1 and VITROS Chemistry Products ASO/RF Performance Verifiers I and II are substantially equivalent to the VITROS Chemistry Products Calibrator Kit 16, VITROS Chemistry Products FS Calibrator 1 and VITROS Chemistry Products RF Performance Verifiers I and II, respectively. The predicate devices were cleared by the FDA (K041863) for IVD use.

5.6 Device description

The quantitative measurement of antistreptolysin O is performed using the VITROS Chemistry Products ASO Reagent in conjunction with the VITROS Chemistry Products Calibrator Kit 28 and VITROS Chemistry Products FS Calibrator 1 on VITROS 5,1 FS Chemistry Systems. The FDA has classified Streptococcus spp. exoenzyme reagents (Sec. 866.3720) in Class I (general controls), therefore, the VITROS Chemistry Products ASO Reagent is exempt from premarket notification procedures in 21 CFR Part 807 Subpart E.

VITROS Chemistry Products Calibrator Kit 28

VITROS Chemistry Products Calibrator Kit 28 is an aqueous solution containing processed human serum, protein, inorganic salt, and preservative.

VITROS Chemistry Products FS Calibrator 1

VITROS Chemistry Products FS Calibrator 1 is composed of processed water and 0.9% w/v sodium chloride (Saline).

VITROS Chemistry Products ASO/RF Performance Verifier I and II

VITROS Chemistry Products ASO/RF Performance Verifiers contain two levels of lyophilized assayed controls for use in monitoring performance of VITROS ASO and RF Reagents on VITROS 5,1 FS Chemistry Systems.

These controls are prepared from processed human serum to which purified human proteins, bovine serum albumin and preservative have been added. These controls are reconstituted with VITROS Chemistry Products FS Reconstitution Diluent that contains processed water.

5.7 Device intended use

VITROS Chemistry Products Calibrator Kit 28

For *in vitro* diagnostic use only.

VITROS Chemistry Products Calibrator Kit 28 is used in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of antistreptolysin O (ASO).

VITROS Chemistry Products FS Calibrator 1

For *in vitro* diagnostic use only.

VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Chemistry Products Calibrator Kits 16, 17, 18, 19, and 28 to calibrate VITROS 5,1 FS Chemistry Systems.

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VITROS Chemistry Products ASO/RF Performance Verifier I and II

For *in vitro* diagnostic use only

VITROS Chemistry Products ASO/RF Performance Verifiers are assayed quality controls used to monitor the performance of VITROS ASO and RF Reagent on VITROS 5,1 FS Chemistry Systems.

5.8 Comparison to predicate device

The VITROS Chemistry Products Calibrator Kit 28, VITROS Chemistry Products FS Calibrator 1, and VITROS Chemistry Products ASO/RF Performance Verifiers I and II are substantially equivalent to the VITROS Chemistry Products Calibrator Kit 16, VITROS Chemistry Products FS Calibrator 1, and VITROS Chemistry Products RF Performance Verifiers I and II, respectively. These predicate devices were cleared by the FDA (K041863) for IVD use.

Tables 1, 2, and 3 provide similarities and differences between the new devices and predicate devices.

Table 1 **Table 1** lists the similarities and differences of the device characteristics between new device, VITROS Chemistry Products Calibrator Kit 28 and predicate device, VITROS Chemistry Products Calibrator Kit 16.

Device Characteristic	VITROS Calibrator Kit 28 New device #1	VITROS Calibrator Kit 16 Predicate device #1
Intended Use	For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 28 is used in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of antistreptolysin O (ASO).	For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 16 is used in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of rheumatoid factor (RF).
Fluid Matrix	Same	An aqueous solution
Analyte Levels	One level	Five levels
Analyte	Antistreptolysin O (ASO)	Rheumatoid factor (RF)
Traceability	NIBSC 97/662[1]	NIBSC 64/2[2]
Format	Same	Liquid ready to use

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Table 2 **Table 2** lists the similarities and differences of the device characteristics between new device, VITROS Chemistry Products FS Calibrator Kit 1 and predicate device, VITROS Chemistry Products FS Calibrator Kit 1.

Device Characteristic	VITROS FS Calibrator Kit 1 New device #2	VITROS FS Calibrator Kit 1 Predicate device #2
Intended Use	For *in vitro* diagnostic use only VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Calibrator Kits 16, 17, 18, 19 and 28 to calibrate VITROS 5,1 FS Chemistry Systems.	For *in vitro* diagnostic use only VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Calibrator Kits 16, 17, 18 and 19 to calibrate VITROS 5,1 FS Chemistry Systems.
Fluid Matrix	Same	Saline and processed water
Analyte Levels	Same	One level
Analyte	Antistreptolysin O (ASO)	Rheumatoid factor (RF)
Traceability	NIBSC 97/662[1]	NIBSC 64/2[2]
Format	Same	Liquid ready to use

Table 3 **Table 3** lists the similarities and differences of the device characteristics between new device, VITROS ASO/RF Performance Verifiers and predicate device, VITROS RF Performance Verifiers.

Device Characteristic	VITROS ASO/RF Performance Verifiers I and II New device #3	VITROS RF Performance Verifiers I and II Predicate device #3
Intended Use	For *in vitro* diagnostic use only. VITROS Chemistry Products ASO/RF Performance Verifiers are assayed controls used to monitor the performance of VITROS ASO and RF Reagents on VITROS 5,1 FS Chemistry Systems.	For *in vitro* diagnostic use only. VITROS Chemistry Products RF Performance Verifiers are assayed controls used to monitor performance of VITROS RF Reagent on VITROS 5,1 FS Chemistry Systems.
Fluid Matrix	Same	A base matrix of processed human serum to which purified human proteins, bovine serum albumin and preservative have been added.
Analyte Levels	Same	Low and High
Analyte	Antistreptolysin O and Rheumatoid factor	Rheumatoid factor
Format	Same	Lyophilized

5.9 Conclusions

The information presented in this premarket notification provide a reasonable assurance that the VITROS Chemistry Products Calibrator Kit 28 when used in conjunction with VITROS Chemistry Systems FS Calibrator 1 and the VITROS Chemistry Products ASO/RF Performance Verifiers I and II are safe and effective for the stated intended uses.

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Ortho-Clinical Diagnostics, Inc. believes that the VITROS Chemistry Products Calibrator Kit 28, VITROS Chemistry Products FS Calibrator 1, and VITROS Chemistry Products ASO/RF Performance Verifiers I and II are substantially equivalent to the VITROS Chemistry Products Calibrator Kit 16, VITROS Chemistry Products FS Calibrator 1, and VITROS Chemistry Products RF Performance Verifiers I and II, respectively. These predicate devices were cleared by the FDA (K041863) for IVD use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 14 2005

Mr. Michael M. Byrne
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k052645
Trade/Device Name: VITROS Chemistry Products Calibrator Kit 28
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products ASO/RF Performance Verifier I and II
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: GTQ
Dated: November 21, 2005
Received: November 22, 2005

Dear Mr. Byrne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052645

Device Name: VITROS Chemistry Products Calibrator Kit 28
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products ASO/RF Performance Verifiers I and II

Indications For Use: For *in vitro* diagnostic use only.
VITROS Chemistry Products Calibrator Kit 28 is used in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of antistreptolysin O (ASO).

For *in vitro* diagnostic use only.
VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Chemistry Products Calibrator Kits 16, 17, 18, 19, and 28 to calibrate VITROS 5,1 FS Chemistry Systems.

For *in vitro* diagnostic use only.
VITROS Chemistry Products ASO/RF Performance Verifiers are assayed controls used to monitor the performance of VITROS ASO and RF Reagent on VITROS 5,1 FS Chemistry Systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052645